

Patent Application

for

**SAFETY NEEDLE ASSEMBLY**

**RELATED APPLICATION**

This application is a continuation of U.S. Patent Appl. No. 10/173,239, filed June 14, 2002.

**FIELD OF THE INVENTION**

[0001] The present invention relates to a shield for a needle and more particularly to a safety shield assembly that may be used in conjunction with a syringe assembly, a hypodermic needle, a needle assembly, a needle assembly with a needle holder, a blood collection needle, a blood collection set, an intravenous infusion set or other fluid handling devices or assemblies that contain piercing elements.

**BACKGROUND OF THE INVENTION**

[0002] Disposable medical devices having piercing elements for administering a medication or withdrawing a fluid, such as hypodermic needles, blood collecting needles, fluid handling needles and assemblies thereof, require safe and convenient handling. The piercing elements include, for example, pointed needle cannula or blunt ended cannula.

[0003] Safe and convenient handling of disposable medical devices is recognized by those in the medical arts so as to minimize exposure to blood borne pathogens. Safe and convenient handling of disposable medical devices results in the disposal of the medical devices intact.

[0004] As a result of this recognition, numerous devices have been developed for shielding needles after use. Many of these devices are somewhat complex and costly.

In addition, many of these devices are cumbersome to use in performing procedures. Furthermore, some of the devices are so specific that they preclude use of the device in certain procedures or with certain devices and/or assemblies. For example, some devices employ very short thin needle cannulas. A shield designed to lock near the distal end of one needle cannula might not engage a much shorter needle cannula. Additionally, a shield designed to lock with a wider gauge needle cannula might be more likely to generate a spray upon engaging a much narrower needle cannula. Furthermore, it may be desirable to reduce the force required to effect shielding without reducing the audible and tactile indications of complete shielding.

[0005] Therefore, there exists a need for a safety shield assembly: (i) that is manufactured easily; (ii) that is applicable to many devices; (iii) that is simple to use with one hand; (iv) that can be disposed of safely; (v) that does not interfere with normal practices of needle use; (vi) that has tactile features whereby the user may be deterred from contacting the needle, the user may easily orient the needle with the patient and easily actuate and engage the shield assembly; (vii) that has visual features whereby the user may be deterred from contacting the needle, the user may easily orient the needle with the patient and easily actuate and engage the shield assembly; (viii) that is not bulky; (ix) that includes means for minimizing exposure to the user of residual fluid leaking from the needle; and (x) provides minimal exposure to the user because the needle shield is immediately initiated by the user after the needle is withdrawn from the patient's vein.

#### **SUMMARY OF THE INVENTION**

[0006] The present invention is a safety shield assembly that comprises: a shield; means for connecting the shield to a fluid handling device that contains a piercing element, such as needle; means for pivoting the shield away from the needle; and means for securely covering and/or containing the needle within the shield.

[0007] Preferably, the shield comprises a rearward end, a forward end, a slot or longitudinal opening for housing the used needle in the forward end, means for securing the needle in the slot, means for guiding the needle into the slot, means for

connecting the shield and the fluid handling device, means for guiding the user's fingers to move the shield into various positions, and means for retaining the shield securely over the used needle.

[0008] Desirably, the means for connecting the shield to the fluid handling device is a collar. Preferably, the shield is connected movably to a collar which is connected to a fluid handling device.

[0009] Preferably, the shield is connected to the collar by a hanger bar that engages with a hook arm on the collar so that the shield may be pivoted with respect to the collar into several positions. It is within the purview of the present invention to include any structure for connecting the shield to the collar so that the shield may be pivoted with respect to the collar. These structures include known mechanical hinges and various linkages, living hinges, or combinations of hinges and linkages.

[0010] Most preferably, the shield is connected to the collar by an interference fit between the hanger bar and the hook bar. Therefore, the shield always is oriented in a stable position and will not move forward or backwards unless movement of the shield relative to the hanger bar and the hook bar is initiated by the user.

[0011] Alternatively, the collar and at least a portion of the shield may be a unitary one-piece structure. The one-piece structure may be obtained by many methods, including molding the shield and the collar as a one-piece unit, thereby eliminating the separate shield and collar during the manufacturing or assembly process.

[0012] The assembly of the present invention may further comprise tactile and visual means for deterring the user from contacting the needle, providing easy orientation of the needle with the patient and providing the user with a guide for actuation and engagement with the shield.

[0013] The assembly of the present invention may further comprise means for minimizing exposure by the user to residual fluid leaking from a used needle. For example, a polymer material, such as a gel, may be located in the shield.

[0014] Most desirably, the assembly of the present invention is such that the cooperating parts of the assembly provide the means for the shield to move into a forward position over the needle. Thus, by simple movement of the shield into a

forward position over the used needle, the assembly is ready for subsequent disposal. Therefore, the safety shield assembly of the present invention provides minimal exposure of the user to a needle because the shielding is initiated by the user immediately after the needle is withdrawn from the patient's vein.

**[0015]** Desirably, the assembly of the present invention may be used with a syringe assembly, a hypodermic needle, a needle assembly, a needle assembly with a needle holder, a blood collection set, an intravenous infusion set or other fluid handling devices. Preferably, the assembly of the present invention is used with a needle assembly comprising a needle and a hub. Preferably the needle is a conventional double ended needle.

**[0016]** Most preferably, the present invention is used with a needle assembly comprising a hub and a needle connected to the hub whereby the needle comprises a non-patient end and an intravenous end. The collar of the present invention may comprise a hook arm and the shield may be connected movably to the hook arm. Thus the shield may be pivoted with respect to the collar and moved easily into several positions.

**[0017]** Preferably, the collar is fitted non-rotatably with the hub of the needle assembly. Additionally, the collar includes cooperating means that mate with reciprocal means on the shield to provide a clear audible and tactile indication of shielding. The cooperating means on the collar may include generally chevron-shaped projection formed on a side of the collar substantially diametrically opposite the hook arm or other such structure that provides the hinge connection to the shield. The chevron-shaped structure includes a forward or distal point. Slanting surfaces diverge and extend proximally from the distal point. The slanting surfaces cooperate with the reciprocal means on the shield to generate a deflection of the sidewalls of the shield away from one another. The chevron-shaped structure further includes proximal ends that are convexly arcuate. The convexly arcuate ends of the chevron-shaped structure on the collar cooperate with the reciprocal means on the shield and with the resiliently deflectable sidewalls of the shield to generate the tactile and audible indication of shielding.

[0018] The shield preferably includes a proximal or rearward portion that is hingedly connected to the collar and a distal or forward portion that comprises a support extending unitarily from the rearward portion of the shield. The shield may further comprise a cannula channel securely mounted to at least the support of the forward portion. The channel may comprise a top wall securely connected to the support of the shield and a pair of opposed spaced apart sidewalls extending downwardly from the top wall. The spacing between the sidewalls is selected to accommodate the needle cannula in the channel. At least one of the sidewalls of the cannula channel is formed with at least one cannula finger lock that projects angularly toward the top wall of the cannula channel. The cannula finger lock is dimensioned, disposed and aligned to contact the needle cannula when the shield approaches the second position. Contact between the needle cannula and the cannula finger lock will cause the cannula finger lock to resiliently deflect toward the sidewall from which the cannula finger lock extends. Sufficient rotation of the shield will cause the needle cannula to pass the cannula finger lock. As a result, the cannula finger lock will resiliently return to or toward its undeflected condition for securely trapping the needle cannula in the shield.

[0019] The top wall of the cannula channel may comprise means for engaging reciprocal means on the support of the forward portion of the shield. The mounting means on the cannula channel may be disposed in a non-central position relative to the longitudinal direction of the channel. Thus, the cannula channel can be mounted to the shield support in either of two alternate orientations that are rotated 180° from one another. In a first rotational orientation, the cannula channel projects distally or forwardly beyond the support of the shield. In a second rotational orientation, the cannula channel projects rearwardly or proximally from the support of the shield to overlie the rearward portion of the shield. Thus, the first rotational orientation of the cannula channel ensures that the pointed distal end of a long needle cannula is surrounded by the cannula channel and engaged by the cannula finger locks. The second rotational orientation of the cannula channel ensures that a shorter needle cannula is surrounded by the cannula channel and engaged by the cannula finger locks.

[0020] The cannula channel may have a proximal or rear end configured for engaging the collar or hub when the shield is in its second position. Engagement of the channel with the collar or hub may contribute to locked retention of the shield in the second position. Additionally, engagement of the proximal end of the cannula channel with the collar or hub may further support the channel and prevent excessive deformation of the channel.

[0021] Preferably, the collar is fitted with the hub of the needle assembly so that the collar cannot rotate around the hub. Alternatively, the collar and hub may be a unitary one-piece structure. The one piece structure may be accomplished by many methods including molding the collar and the hub as a one-piece unit thereby eliminating the need to separately assemble the collar to the hub during the manufacturing process.

[0022] Most preferably, the collar is fitted with the hub of the needle assembly so that the bevel surface or bevel up surface of the intravenous or distal end of the needle faces the same side of the collar when the shield is in the first position. Alignment of the collar, hub, shield and needle with the bevel surface up makes it easier to insert the needle into the patient without manipulating the assembly. The orientation of the intravenous end of the needle with the bevel up assures the user that the needle is properly oriented for use and does not require any manipulation before use. Most notably, the orientation of the shield provides a visual indication to the user of the orientation of the bevel surface of the needle.

[0023] Preferably, the shield is capable of pivoting from a first position where the intravenous end of the needle is exposed and bevel up, to an intermediate position where the needle is partially covered, to a second position where the needle is covered completely.

[0024] Alternatively, it is within the purview of the present invention that the collar, hub and at least a portion of the shield may be a unitary one-piece structure. The one-piece structure may be accomplished by many methods including molding the shield, collar and hub as a one-piece unit thereby eliminating the need to separately assemble the shield, collar and hub during the manufacturing process.

[0025] It is an advantage of the present invention that the shield covering the used intravenous end of the needle provides easy containment of the used needle. A further advantage of the shield is that it will only move upon initiation by the user.

[0026] The assembly of the present invention when used with a fluid handling device is also easily disposable when removed from a conventional needle holder, or other such device.

[0027] A notable attribute of the present invention is that it is easily adaptable with many devices. For example, the invention is usable with syringe assemblies, hypodermic needles, needle holders, blood collection needles, blood collection sets, intravenous infusion sets such as catheters or other fluid handling devices or assemblies that contain piercing elements.

[0028] Another notable attribute of the present invention is that the tactile and visual features deter the user from touching the needle, allow the user to easily orient the needle with the patient and guide the user to actuate and engage the shield of the assembly.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

[0029] FIG. 1 is a perspective view of the safety shield assembly of the present invention as connected to a needle assembly and related packaging features.

[0030] FIG. 2 is a perspective view of the unassembled pieces of FIG. 1.

[0031] FIG. 3A is a bottom view of the shield as shown in FIG. 2.

[0032] FIG. 3B is an enlarged bottom view of an ear of the shield.

[0033] FIG. 4 is a cross sectional view of the collar as shown in of FIG. 2 taken along lines 4-4 thereof.

[0034] FIG. 5 is a cross sectional view of the needle hub as shown in FIG. 2 taken along lines 5-5 thereof.

[0035] FIG. 6A is a cross sectional view of the shield of FIG. 2 taken along lines 6A-6A thereof.

[0036] FIGS. 6B is a cross-sectional view similar to FIG. 6A, but showing the cannula channel in an end-to-end reversed orientation.

[0037] FIGS. 7-12 illustrate the use of the safety shield assembly with the needle assembly of FIG. 1 with a conventional needle holder.

[0038] FIG. 13 is a cross-sectional view of the assemblies in use with a conventional needle holder as shown in FIG. 12 taken along lines 13-13 thereof.

[0039] FIG. 14 is a cross-sectional view of the assemblies of FIG. 13 taken along lines 14-14 thereof.

[0040] FIG. 15A is a bottom view of the assemblies as shown in FIG. 11.

[0041] FIG. 15B is an enlarged bottom view showing the engagement of the ear and the chevron-shaped projection.

[0042] FIG. 16 illustrates an additional embodiment of the present invention, whereby a gel material is located in the shield as shown in a bottom view of the assemblies of FIG. 11.

[0043] FIG. 17 is a perspective view of an additional embodiment of the present invention in use with a blood collection set.

[0044] FIG. 18 is a perspective view of an additional embodiment of the present invention in use with a syringe.

[0045] FIG. 19 is a perspective view of an additional embodiment of the present invention in use with a catheter.

[0046] FIG. 20 is an exploded side elevational view of an additional embodiment of the present invention.

[0047] FIG. 21 is a bottom view of the clip of FIG. 20.

[0048] FIG. 22 is a bottom view of the assembly similar to FIG. 15A, but showing an additional embodiment of the present invention without a chevron-shaped structure on the collar and without locking ears on the shield.

#### **DETAILED DESCRIPTION OF THE INVENTION**

[0049] While this invention is satisfied by embodiments in many different forms, there is shown in the drawings and will herein be described in detail, the preferred embodiments of the invention, with the understanding that the present disclosure is to be considered as exemplary of the principles of the invention and is not intended to



limit the invention to the embodiments illustrated. Various other modifications will be apparent to and readily made by those skilled in the art without departing from the scope and spirit of the invention. The scope of the invention will be measured by the appended claims and their equivalents.

[0050] Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, FIGS. 1 and 2 illustrate a needle assembly with the safety shield assembly of the present invention and the related packaging features. The needle assembly includes a needle 40, a hub 60, packaging features to cover the needle and a label. The safety shield assembly includes a collar 90 and a shield 140.

[0051] As shown in FIG. 2 and 5, needle 40 includes a non-patient end 42, an intravenous end 44 and a passageway 46 extending between the non-patient end and the intravenous end. An elastomeric sleeve 48 covers the non-patient end. A first rigid sleeve 50 covers the intravenous end and a second rigid sleeve 52 covers the non-patient end and the elastomeric sleeve. As shown in FIG. 1, a label 196 may also be applied to the finally assembled parts.

[0052] As shown in FIGS. 2 and 5, hub 60 includes a threaded end 64, a ribbed end 66 and passageway 62 extending between the threaded end and the ribbed end. Threaded end 64 and ribbed end 66 are separated by flange 68. Non-patient end 42 of needle 40 extends from threaded end 64 and intravenous end 44 of needle 40 extends from ribbed end 66. Preferably, threaded end 64 comprises male threads 80 for mounting the hub on a conventional needle holder and ribbed end 66 comprises male ribs 82 for connecting the hub and collar 90.

[0053] As shown in FIGS. 2 and 4, collar 90 includes a forward skirt 92 and a rearward skirt 94. Forward skirt 92 is cylindrical and comprises an inner circumferential surface 96 and an outer circumferential surface 98. Forward skirt 92 mates with rearward skirt 94 at a shoulder 100. Rearward skirt 94 is cylindrical and comprises an inner circumferential surface 102 and an outer circumferential surface 104 and extends from shoulder 100 opposite of forward skirt 92. The inner diameter of forward skirt 92 is larger than the inner diameter of rearward skirt 94. Alternatively, the inner diameters for collar 90 can be equal. A hook 114 extends from outer circumferential surface 98

of forward skirt 92. Additionally a chevron-shaped protrusion 118 projects outwardly from outer circumferential surface 98 of forward skirt 92 at a side opposite hook 114. The chevron-shape protrusion 118 is substantially symmetrical and has a peak 120 pointed toward forward skirt 92 and ramp surfaces 122 that diverge symmetrically from peak 120 toward rearward skirt 94. Ramp surfaces 122 terminate at rounded ends 124 at the outer side and proximal extremes of chevron-shaped protrusion 118. Rounded ends 124 extend continuously into the proximal side of chevron-shaped protrusion 118 facing toward rearward skirt 94.

[0054] As shown in FIGS. 2 and 6, shield 140 comprises a rearward end 144 and a forward end 146. Forward end 146 of shield 140 defines an elongate support wall 150 with a distal end 152 and top and bottom surfaces 154 and 156 extending proximally from distal end 152. In the illustrated embodiment, top and bottom surfaces 154 and 156 are slightly arcuate from side-to-side. However, in other embodiments, top surface 154 and/or bottom surface 156 may be substantially planar. Support wall 152 is characterized by axially spaced apertures 158 extending entirely therethrough from top surface 154 to bottom surface 156.

[0055] Rearward end 144 of shield 140 defines a collar engaging area 166. Collar engaging area 166 includes a rearward end 168, a forward end 170, a top finger guide area 172, sidewalls 174 that extend downwardly from top finger guide area 172, an underside area 176 dimensioned for surrounding collar 90, and extending arms 180 to support hanger bar 182. Sidewalls 174 are spaced apart by a major width adjacent rearward end 168. The major width is selected to enable sidewalls 174 to slide across diametrically opposite side surfaces of forward skirt 92 of collar 90. Sidewalls 174 converge, however, toward forward end 170 to define a minor distance therebetween. Sidewalls 174 include bottom edges 177 that face away from top finger guide area 172. As shown most clearly in FIG. 6, bottom edges 177 curve toward top finger guide area 172 at locations between rearward end 168 and forward end 170 of collar engaging area 166.

[0056] Shield 140 further includes a cannula channel 220. Cannula channel 220 includes opposed longitudinal ends 222 and 224, an elongate convex outer surface 226

extending between ends 222 and 224 and an inner concave surface 228 extending between ends 222 and 224. An entry to concave inner surface 228 is defined by opposed parallel edges 230 that extend substantially between ends 222 and 224 of channel 220. Mounting projections 232 project from convex outer surface 226 at a location substantially equally spaced from edges 230. Thus, mounting projections 232 are substantially opposite from the entry into concave inner surface 228 of channel 220. Mounting projections 232 are spaced from one another by a distance substantially equal to the spacing between mounting apertures 158 in support wall 150. Additionally, mounting projections 232 are dimensioned to be snapped or force fit into apertures 158. Mounting projections 232 are not symmetrically disposed along the length of cannula channel 220. Rather, mounting projections 232 are closer to end 222 than to end 224. Channel 220 is defined further by cannula finger locks 234 that project obliquely inwardly from one of side edges 230. Cannula finger locks 234 are resiliently deflectable in response to forces exerted by needle 40 as explained further below.

[0057] The extreme rear ends of sidewalls 174 on collar engaging area 166 include rounded ears 194 that project toward one another from opposed inner surfaces 175 of sidewalls 174. Rounded ears 194 are disposed to engage chevron-shaped projection 118 on collar 90. More particularly, each rounded ear 194 includes a distal surface 195, a proximal surface 197 and a curved surface 198 extending between distal and proximal surfaces 195 and 197. Distal surface 194 is aligned to sidewall 174 at a rake angle of approximately 60° and proximal surface 197 is aligned to sidewall 174 at an angle of approximately 45°. Curved surface 198 extends smoothly and convexly between distal and proximal surfaces 195 and 197. Proximal surfaces 197 of rounded ears 194 will engage ramp surfaces 122 of chevron-shaped projection 118 to deflect sidewalls 174 slightly away from one another as shield 140 approaches the second position. The apex of curved surface 198 on each rounded ear 194 passes the respective rounded end surface 124 on chevron-shaped projection 118 on collar 90. As a result, sidewalls 174 begin to return resiliently toward an undeflected condition. The resilient return of sidewalls 174 and raked distal surface 195 of ears 194 causes sidewalls 174 to snap against chevron-shaped projection 118. This snapping action provides a clear audible

and tactile indication of complete shielding and occurs substantially when the used needle is trapped by cannula finger locks 234. The angles of distal and proximal surfaces 195 and 197 of rounded ears 194 affects the performance of shield 140. In particular, a smaller acute angle alignment of proximal face 197 reduces the force required to move shield 140 passed rounded ears 194. A larger acute angle proximal surface 197 of rounded ears 194 requires a greater force to move shield 140 toward the second position. Similarly, the angle between distal surface 195 and sidewall 174 affects the acceleration characteristics as shield 140 is propelled toward the second position in response to the resilient return of sidewalls 174. This change in acceleration characteristics affects the audible indication of shielding. Different audible and acceleration characteristics can be achieved by employing more sharply pointed corners on the end surface of chevron-shaped projection 118 for engagement by rounded ears 194 of shield 140.

[0058] Top finger guide area 172 comprises a first ramp 184 that extends slightly on an upwardly slope from the rearward end of the collar engaging area to a shoulder 186. From shoulder 186 extends a second ramp 188 which slopes downwardly towards support wall 150. Most preferably, first ramp 184 comprises touch bumps 190. The touch bumps provide a tactile and visual guide to alert the user that the user's finger has contacted the shield and that the shield is in a defined or controlled position. The touch bumps may be any configuration so long as they extend and are distinct from the top finger guide area. The touch bumps may also be of a distinguishing color as compared to the top finger guide area or the shield.

[0059] Second ramp 188 has interior surface 192 for urging the needle toward the center as the shield is being rotated into the closed position. The exterior surfaces are slightly inclined and extending radially from the second ramp. The interior surfaces are especially helpful if the longitudinal axis of the needle is misaligned with respect to the longitudinal axis of the hub.

[0060] Extending arms 180 are located at rearward end 168 and at the beginning of top finger area 172 and hold hanger bar 182.

[0061] The safety shield assembly and the needle assembly are assembled together whereby needle 40 is connected to hub 60 and sealed with adhesive at the ends of the hub. Hub 60 is then joined with collar 90 by ultra-sonic welding techniques or any other bonding techniques, or mechanical fit, whereby rearward annular skirt 94 of collar 90 mates with ribbed end 66 of the hub. Male ribs 82 of the hub are contained or forced fitted within inner sidewall 102 of rearward annular skirt 94 of collar 90. The collar is aligned with the intravenous end of the needle whereby the hook arm is aligned with the bevel up of the needle. Then rigid sleeve 50 is force fitted into inner side wall 96 of forward skirt 92 of collar 90 to cover the needle. Channel 220 then is mounted to support wall 150. More particularly, as shown in FIGS. 2, 3 and 6A, channel 220 is oriented such that end 224 of channel 220 projects distally or forwardly beyond support wall 150. This orientation is appropriate in situations where it is known that a relatively long needle cannula will be employed with the needle assembly. Alternatively, however, channel 220 can be oriented as shown in FIG. 6B so that end 222 of channel 220 is aligned substantially with the distal end 152 of support wall 152 while end 224 of channel 222 projects rearwardly or proximally into rearward end 144 of shield 140. Thereafter, shield 140 is connected to collar 90 whereby hanger bar 182 is force fitted into hook member 114 whereby slot 160 faces rigid sleeve 50. Most preferably, the shield is connected to the collar by a force fit or interference fit between the hanger bar and the hook bar. Therefore, the shield is always oriented in a stable position and will not move unless movement of the shield is positively initiated by the user. To assemble the last piece, shield 140 is moved towards rigid sleeve 50 and second rigid sleeve 52 is force fitted onto outer sidewall 104 of rearward skirt 94 of collar 90.

[0062] In addition, a label 196 may be applied to the finally assembled parts. The label may be used to prevent tamper resistance of the parts, so that they are not reused.

[0063] In use, as shown in FIGS. 7-15, the non-patient needle shield is removed and then a needle holder is screwed onto the hub of the needle. As specifically shown in FIGS. 8 and 12 the shield is then rotated back by the user towards the needle holder. Then as shown in FIG. 9, the intravenous needle shield is removed from covering the

intravenous needle. Then as shown in FIG. 10, a venipuncture is conducted whereby the intravenous end of the needle is inserted into a vein of a patient and an evacuated tube having a closure is inserted into the needle holder. Then as shown in FIGS. 11 and 13, when the venipuncture is complete the user easily rotates the shield from the first position towards the intravenous needle to an intermediate position and then the user pushes on the shield at the top finger guide area to move the shield into a second position whereby the needle is trapped in the longitudinal opening. More particularly, needle **40** contacts cannula finger locks **234**. Accordingly, cannula finger locks **234** deflect toward support wall **150** and away from edges **230**. Sufficient rotation of shield **140** will cause needle **40** to pass cannula finger locks **234**. As a result, cannula finger locks **234** will return resiliently to an undeflected condition. Thus, needle **40** will be trapped above cannula finger locks **234**.

[0064] Needle **40** is contained within shield **140** as the shield is pivoted into the closed position. More particularly, proximal surfaces **197** of rounded ears **194** move over ramp surfaces **122** of chevron-shaped projection **118** and cause sidewalls **174** to deflect away from one another. The angularly aligned proximal faces **197** of rounded ears **194** ensure easy movement of shield **140**. Additionally, the resiliency of sidewalls **174** and the angular alignment of distal surface **195** of ears **194** causes a cooperation with rounded proximal ends **124** of chevron-shaped projection **118** to accelerate shield **140**. This accelerated movement of shield **140** helps to generate a clear audible and tactile indication of complete shielding.

[0065] FIGS. 17, 18, and 19 are further embodiments of the invention that include may components which are substantially identical to the components of FIGS. 1-3. Accordingly, similar components performing similar functions will be numbered identically to those components of FIGS. 1-3, except that a suffix "a" will be used to identify those similar components in FIG. 17, a suffix "b" will be used to identify those similar components in FIG. 18 and a suffix "c" will be used to identify those similar components in FIG. 19.

[0066] Alternatively, the safety shield assembly of the present invention may be used in conjunction with a conventional intravenous (IV) infusion set, as illustrated in FIG. 17.

[0067] For purposes of illustration, shield **140a** and collar **90a** are connected to a conventional IV infusion set, **200**, or butterfly structure comprising a needle body with a needle hub **204** extending from the forward end of the needle body and a needle **206** embedded in hub **204**. Extending from the rearward end of the needle body is flexible tubing **208** which is conventional and utilized to allow the user to manipulate the structure and to connect it subsequently to supplies of infusion liquids or for the return of collected blood if the arrangement is being used to collect blood.

[0068] Infusion set **200** further comprises flexible wings **210** attached to and projecting outwardly from needle hub **204**.

[0069] Alternatively, the safety shield assembly of the present invention may be used in conjunction with a syringe, as illustrated in FIG. 18.

[0070] For purposes of illustration, shield **140b** and collar **90b** are connected to a conventional hypodermic syringe **300** comprising a syringe barrel **302** having a distal end **304** a proximal end **306** and a plunger **312**.

[0071] Alternatively, the present invention may be used in conjunction with a catheter as illustrated in FIG. 19.

[0072] FIGS. 20 and 21 show a further alternate to the needle assemblies described and illustrated above. In particular, the embodiment of FIGS. 20 and 21 includes a shield **140d** that is similar to the shield **140** described and illustrated above. Shield **140d** includes a collar engaging area **166d** with a top finger guide area **172d** and sidewalls **174d** that extend downwardly from top finger guide area **172d**. Sidewalls **174d** differ from the embodiments described and illustrated above in that they extend a shorter distance from top finger guide area **172d** and have no means for engaging the chevron-shaped projection on the collar.

[0073] Shield **140d** includes a forward end **146d** with a top wall **163d** and sidewalls **162d** extending down from top wall **163d**. Top wall **163d** is characterized by spaced apart mounting apertures **164d**.

[0074] Shield **140d** further includes a channel-shaped clip **220d** having a proximal end **222d**, a distal end **224d** and a top wall **226d** extending from distal end **224d** toward proximal end **222d**. The top wall includes a pair of spaced apart mounting projections **228d** that are dimensioned to be mounted in mounting apertures **158d** on forward end **146d** of shield **140d**. Cannula finger locks **230d** extend from the channel-shaped clip in a direction away from mounting projections **228d**. Each cannula finger lock **230d** includes a support leg and a cannula engaging leg **234d**. Cannula finger locks **230d** are dimensioned and configured to trap the needle cannula when shield **140d** is rotated into the closed position.

[0075] Proximal end **222d** of clip **220d** includes a pair of collar engaging legs **236d** extending generally proximally from top wall **226d**. Cannula engaging legs **236d** are configured to pass around opposite respective sides of the collar. Ends of collar engaging legs **236d** furthest from top wall **226d** are formed with rounded ears **238d**. Ears **238d** are configured to snap into engagement with the chevron-shaped projection, as described above.

[0076] Shield **140d** is used substantially exactly as shield **140** described above. In particular, shield **140d** can be rotated from the open position to the closed position. As shield **140d** approaches the closed position, cannula engaging legs **234d** of cannula locking fingers locks **230d** engage the needle cannula. Simultaneously, rounded ears **238d** engage the chevron-shaped projection. The rounded configuration of ears **238d** helps to propel shield **140d** toward the closed position. In the closed position, cannula finger locks **230d** will snap past the needle cannula for permanently trapping the needle cannula within shield **140d**.

[0077] The shield and collar of the safety shield assembly of the present invention are comprised of moldable parts which can be mass produced from a variety of materials including, for example, polyethylene, polyvinyl chloride, polystyrene or polyethylene and the like. Materials will be selected which will provide the proper covering and support for the structure of the invention in its use, but which will provide also a degree of resiliency for the purpose of providing the cooperative movement relative to the shield and the collar of the assembly.



[0078] A further alternate embodiment is illustrated in FIG. 22, and is virtually identical to the embodiment of the invention depicted in FIG. 15A. As a result, comparable numerals have been employed to identify identical or very similar components. FIG. 22, however, differs from FIG. 15A in that collar **90** does not have the chevron-shaped protrusion **118** illustrated in FIG. 15A. Additionally, shield **140** does not have ears comparable to rounded ears **194** of FIG. 15A. Thus, the embodiment illustrated in FIG. 22 relies entirely upon the engagement of cannula finger locks **234** with needle **40**. There are fewer structures on the embodiment of FIG. 22 to achieve the clear audible and tactile indication of complete shielding as in the previous embodiment and no structure for accelerating shield **140** in to the second position around needle **40**. However, upon complete shielding, the retention between shield **140** and needle **40** in the embodiment of FIG. 22 is comparable to the retention achieved by the previous embodiments.